

VIA HAND DELIVERY SEPTEMBER 14, 2001

#20/jru
09-26-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Ebner et al.

Attorney Docket No.: PF399

Application Serial No.: 09/115,832

Art Unit: 1647

Filed: July 15, 1998

Examiner: Hamud, F.

Title: Interleukin-20

RECEIVED
SEP 19 2001
TECH CENTER 1600/2900

RESPONSE UNDER 37 C.F.R. § 1.111

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Official Action mailed May 17, 2001 (Paper No. 18), Applicants respectfully request consideration of the following remarks. Applicants submit concurrently herewith (a) a Fee Transmittal Sheet; and (b) a Petition for an Extension of Time for a period of time of one month up to and including September 17, 2001.

Claims 23-38 and 41-48 are pending; the Examiner has indicated that all claims are allowable with the exception of claim 23(o). *See* Paper No. 18, page 3. Applicants thank the Examiner for the recent opportunity to discuss this case by telephone, and respectfully request reconsideration of the instant rejection in view of the following remarks.

Rejection of Claims 23, 38, and 41-48 Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 23, 38, and 41-48 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. (*See* Paper No. 18, pages 2-3). In particular, the Examiner has rejected claim 23(o),

contending that the “instant specification fails to describe the structure of the ‘mature’ Interleukin-20” encoded by the deposited clone.

Applicants respectfully disagree and traverse this rejection.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02. The Federal Circuit recently re-emphasized the well-settled principle of law that “[t]he written description requirement does not require the applicant ‘to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed,’” *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000). While the applicant must “blaze marks on trees,” rather than “simply [provide] the public with a forest of trees,” an Applicant is not required to explicitly describe each of the trees in the forest. *See Unocal*, 208 F.3d at 1000. *See also* M.P.E.P. § 2163.02 (“The subject matter of the claim need not be described literally (i.e., using the same terms or in haec verba) in order for the disclosure to satisfy the description requirement.”). The Court emphasized the importance of what the person of ordinary skill in the art would understand from reading the specification, rather than whether the specific embodiments had been explicitly described or exemplified. Indeed, as the court noted, “the issue is whether one of skill in the art could derive the claimed ranges from the patent’s disclosure.” *Unocal*, 208 F.3d at 1001 (emphasis added).

In an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability. This

burden is only discharged if the Examiner can present evidence or reasons why one skilled in the art would not reasonably conclude that Applicants possessed the subject matter as of the priority date of the present application. See *In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q.2d 90, 96 (C.C.P.A. 1976); M.P.E.P. § 2163.04. In the instant case, Applicants submit that the Examiner has not met this burden.

Applicants respectfully disagree with the Examiner and submit that one skilled in the art could reasonably conclude that Applicants had possession of the nucleotides encompassed by the rejected claims in the present application as filed. Applicants point out that the Examiner has recognized that the specification “provide[s] a deduced amino acid sequence for IL-20 and predict[s] a leader sequence of about 20 amino acids, (see figure 1).” Paper No. 18, page 3. Indeed, the specification describes the method by which the instant mature form was determined in detail. See page 9, line 30, to page 10, line 26. The specification further teaches that ATCC Deposit No. 209232 contains a plasmid that contains the full-length IL-20 cDNA. See page 8, lines 9-14. Accordingly, expression of the deposited plasmid would inherently produce the mature polypeptide. Thus, one of skill in the art would immediately grasp that Applicants “invented what is claimed.” *Vas-Cath*, 935 F.2d at 1563.

While the Examiner alleges that “the skilled artisan cannot envision the structure of a ‘mature IL-20’, because the protein might be differentially processed depending on which tissue it is expressed in,” no evidence is provided that there are any mature proteins that would differ from those disclosed in the specification. However, even assuming *arguendo* that in some hypothetical cell line, the instant protein would be differentially processed to produce a different mature form, Applicants point out that by disclosing a plasmid that inherently encodes the mature form of the protein, the specification

necessarily discloses the genus of mature forms generated by expression of the plasmid. See M.P.E.P. § 2163.07(a). Indeed, the specification specifically teaches that “the cleavage specificity of a secreted protein is ultimately determined by the primary structure of the complete protein, that is, it is inherent in the amino acid sequence of the polypeptide.” Page 10, lines 2-3 (emphasis added). Moreover, Applicants submit that as of the priority date of the instant invention, it would clearly be routine for one of skill in the art to sequence the N-terminal portion of the mature polypeptide thus generated, allowing for confirmation of the sequence of any expressed mature polypeptide species within the genus, assuming *arguendo* that there is more than one mature form generated by expression of the plasmid in different tissues.

Accordingly, from reading the specification, the skilled person would immediately recognize that, at the time the specification was filed, the Applicants had “invented what is claimed” (*Vas-Cath*, 935 F.2d at 1563); namely, the nucleic acid sequence encoding the mature polypeptide encoded by the cDNA of the deposit. Therefore, the specification contains an adequate written description of the claimed nucleic acid.

For all of the above reasons, Applicants respectfully assert that the Examiner has failed to meet the required burden in presenting evidence or reasons why those skilled in the art would not recognize the claimed invention from the disclosure. Moreover, the specification conveys with reasonable clarity that Applicants were in possession of the claimed invention. Thus, Applicants submit that the pending claims fully meet the written description requirements of 35 U.S.C. § 112, first paragraph, and respectfully request that the Examiner’s rejection of claims 23, 38, and 41-48 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

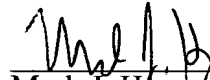
Conclusion

In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for in the Petition for an Extension of Time submitted concurrently herewith, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: September 14, 2001



Mark J. Hyman
Attorney for Applicants

(Reg. No. 46,789)

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
Telephone: (240) 314-1224

Enclosures